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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,179	02/01/2002	William A. Horne	480140.428C1	3580

500 7590 04/21/2006

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/066,179	HORNE ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30, 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 33-34.

Accordingly, claims 30, 32 are being examined.

The following are the remaining rejections.

### **REJECTION UNDER 35 USC 102(e)**

Claims 30, 32 remain rejected under 35 USC 102(e) as being anticipated by US 5,622,852 for the reasons already of record in paper of 07/28/05.

Applicant argues that the Examiner fails to demonstrate that the antibodies of US 5,622,852 would inherently bind to a human BAD polypeptide.

Applicant argues that the claimed human BAD only shares 75% amino acid sequence identity with the murine BAD of US 5,622,852. Applicant argues that in Kamarck, the CEA proteins share substantial homology. Applicant argues that for example, NFA-2 is almost indistinguishable from CEA, and that some of the CEA-related antigens have a high degree of amino-terminal sequence homology.

Applicant argues that while the full length sequences share 58% identity, Banki specifically notes that there are blocks of 11-15 amino acids in which the identity is 100%. Applicant argues that of the two polyclonal antibodies to human transaldolase, only one exhibits cross-reactivity with yeast transdolase, demonstrating that it is not a foregone conclusion that antibodies generated against one protein will necessarily

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cross-react with a homolog with a different species, particularly when there exists a relatively low degree of sequence identity between the murine and human BAD polypeptide.

Applicant's arguments in paper of 01/30/06 have been considered but are found not to be persuasive for the following reasons:

It is noted that the claimed human BAD shares 75% amino acid sequence identity with the murine BAD of US 5,622,852, where there are several stretches of 100% amino acid identity, of 12, 14, 18 and 31 amino acids from a full length sequence of 168 amino acids, especially in important regions such as the BH1 region, or the fragment that binds to Bcl-XL or Bcl-2. For example, from a total of 24 amino acids of the BH1 region (amino acids 137-160 of mouse BAD, within the 95 C-terminal amino acids of the claimed SEQ ID NO:2, i.e. amino acids 74-168 of SEQ ID NO:2), there is only a difference of two amino acids at the end of the BH1 region, amino acids 159-160 (see MPSRCH search report, of record).

Thus, the cross-reactivity of an antibody, due to shared epitopes, as taught by Paul, Kamarck, and Banki, all of record, would apply here as well.

It is further noted that as written the claims are not drawn to a monoclonal antibody that binds to a specific epitope of SEQ ID NO:2.

Thus the monoclonal antibody taught by the art seems to be the same as the claimed monoclonal antibody, and would bind to SEQ ID NO:2 or the 95 C-terminal amino acids of SEQ ID NO:2, via extensive shared epitopes.

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Although the reference does not specifically teach that the monoclonal antibody specifically binds to SEQ ID NO:2, or to the 95 C-terminal amino acids of SEQ ID NO:2, however, the claimed monoclonal antibody appears to be the same as the prior art monoclonal antibody. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER

MINH TAM DAVIS

April 04, 2006